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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,084	04/10/2002	Kazumi Ohtomo	402740/FUJISAWA	2940
23548	7590	11/03/2004	EXAMINER	
LEYDIG VOIT & MAYER, LTD 700 THIRTEENTH ST. NW SUITE 300 WASHINGTON, DC 20005-3960			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,084

Applicant(s)

OHTOMO ET AL.

Examiner

Gollamudi S Kishore, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5-28-04</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

The change of address dated 1-3-03 and the change of power of attorney dated 8-4-03 are acknowledged.

Claims included in the prosecution are 1-12.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 defines a process of producing the liposome preparation. Line 3 of claim already defines the starting product as 'liposome condensed solution'. Then what is prepared as the final product? Is it a powder? Also unclear is what bubbling is intended to convey. Bubbling with a gas?

Claims 3 and 4 are confusing. According to claim 1, the vacuum drying is done without freezing the condensed solution. However, claims 3 and 4 recite temperatures, which are well below freezing temperatures.

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It is unclear as to what is being intended by the expression "while flowing or after flowing the condensed solution" as recited in claim 5. Clarification is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5-6, 9-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/22298 (UNGER et al) of record.

WO discloses a method of preparation of liposomes. The method involves cooling the liposomes to below 0 degrees C (to about – 20 degrees C) and subjecting to negative pressure (vacuum). Upon reaching the desired negative pressure, the liposome temperature is increased. The process proceeds till all of the liquid has been removed from the liposomes (page 20, lines 12-25, Examples 1 and 3 and claims).

5. Claims 1, 5-6, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 86/01103 or JP 06 315623 both are of record.

Just as WO 92, WO 86 and JP disclose a method of preparation of liposomal preparations subjecting the solution of liposomes to vacuum drying without freezing (note page 8, lines 1-17; page 13, lines 20-26, Example 1 and claims in WO and abstract of JP).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/22298 or WO 86/01103 or JP 06 315623 cited above, further in view of EP 658344 also of record.

The method of preparation of liposomes using vacuum drying without freezing disclosed by WO 92, 86 and JP have been discussed above. These references however, do not teach pipecolic acid derivatives as the active agents to be encapsulated in the liposomes.

EP (658344) discloses the pipecolic acid derivative, FK 506 encapsulated in liposomes. EP further teaches that the liposome preparations can be lyophilized (freezing and vacuum drying) (page 5, line 49 through page 6, line 55; Examples and claims).

The reference of EP in essence shows the knowledge in the art of encapsulating pipecolic acid derivatives in liposomes. It would have been obvious to one of ordinary skill in the art with a reasonable expectation of success to use pipecolic acid taught by EP as the active agent and encapsulate it within the liposomes and subject it to vacuum drying method of WO 92, 86 or JP since it would result in the same powder formation. Alternately, to use the powder preparation method without freezing taught by WO 92, 86

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or JP in the teachings of EP would have been obvious to one of ordinary skill in the art since such a method also results in the liposomal powder preparations and because of WO 86's teachings that the method is gentler without a freezing step and thus there is in general less damage to the liposomes (page 8, lines 8-12)


EP does not appear to teach all of the claimed derivatives falling within the claimed generic formula. However, in view of the prior art's teachings of several derivatives containing pipecolic acid which are encompassed in the generic structure of FK -507, in the absence of showing unexpected results, it is deemed obvious to encapsulate any other derivative of pipecolic acid with the expectation of similar encapsulation and similar results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, PhD
Primary Examiner
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GSK